

REMARKS

This is in response to the Office Action mailed 8/01/2007. A request for two-month extension is included herewith.

Claims 1-9,16-18, 28-31, 35-37, 39-47 and 52-54 were again rejected under 35 USC § 103(a) as being unpatentable over WO 96/08229 ('229) by itself or in view of US 5,993,849 ('849).

Without wishing merely to rehash previous arguments, Applicants respectfully request the Examiner's reconsideration of two key points.

First, with regard to the '229 disclosure itself, Applicants' position is not only that '229 alone is insufficient for one of ordinary skill in the art to have believed with reasonable expectation of success that 8-30% fentanyl would fully dissolve in the claimed compositions. Applicants also submitted a clear teaching away from any such expectation, which was not addressed in the Office Action. Roy et al., "Controlled Transdermal Delivery of Fentanyl: Characterizations of Pressure-Sensitive Adhesives for Matrix Patch Design," Pharm Sci. 85(5):491 (1996), disclosed that compositions containing over 4% fentanyl were observed to have dissolved fentanyl and undissolved fentanyl particles. Roy et al. is directly relevant here because it is specifically about fentanyl formulation and clearly teaches away from any general perception of obviousness based the '229 alone.

Second, with regard to the '849 disclosure, reliance on implied equivalence of fentanyl and nicotine is not appropriate in the present context because nicotine is already a *liquid* at room temperature (see Table 1 of Naik et al. showing melting point <-80°C), so unlike fentanyl (which is a crystalline solid) there would be no possible issue about undissolved nicotine particles remaining. Moreover, as shown in Table 1 of Naik et al., aqueous solubility of the two drugs is vastly different (100 mg/ml for nicotine versus only 0.2 mg/ml for fentanyl), so again one skilled in the art would never realistically have viewed a disclosure about nicotine formulation as meaningful to understanding formulation of fentanyl. See also MPEP 2144.06.

Please reconsider the application in view of the above. The undersigned would welcome the opportunity to discuss the matter by phone or in person interview if the Examiner feels it might help to address any of the outstanding issues.

Respectfully submitted,

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